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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/675,020	09/29/2003	Stephen Donovan	17510DIV1 (BOT)	4829

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EXAMINER	
FORD, VANESSA L	
ART UNIT	**PAPER NUMBER**
1645	

DATE MAILED: 06/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/675,020	DONOVAN, STEPHEN	
	Examiner	Art Unit	
	Vanessa L. Ford	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 March 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *16-21 and 36-44* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *16-21 and 36-44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 9/29/05.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 13, 2006 has been entered. Claims 1-15 and 22-25 have been cancelled. Claims 16-21 and 36-44 are pending and under examination.

2. The text of those sections of the Title 35, U.S. code not included in this action can be found in the prior Office Action.

Rejection Withdrawn

3. In view of Applicant's response the rejection of claims 16-21, 39 and 44 under 35 U.S.C. 102(e), pages 2-4,paragraph 3 of the Final Office action is withdrawn.

Rejection Maintained

4. The rejection under 35 U.S.C. 103(a) is maintained for claims 16-21 and 36-44 for the reasons set forth on pages 4-6, paragraph 6 of the Final Office Action.

The rejection was on the grounds that Yuzhakov et al teach a transdermal patch (columns 3-4) comprising a pharmaceutical composition, which comprises a botulinum (column 51, lines 56-63), an enhancing agent (polymers) (column 28) and an adhesive to hold the patch in place (column columns 46 -47). Yuzhakov et al teach that the transdermal patch contains a microneedle array (column 3). Yuzhakov et al teach that the invention is projected or penetrates the stratum corneum (column 3).

Yuzhakov et al do not teach a transdermal patch wherein the enhancing agent is ethanol or comprises transfersomes.

Cevc teaches that solvents such as ethanol (enhancing agents) can be used to induce or increase the carrier system's capacity to form edges, protrusions or relatively strongly curved surfaces; this property also manifests itself in the capability to induce pores in lipid structures, such as membranes, or even provoke a solubilization (lysis) in the higher concentrations ranges (columns 7-8). Cevc teaches that the transfersome compositions of the invention can be introduced not only to a permeability barrier such as the skin (column 4, 66-67 and column 5, lines 1-4). Cevc teaches compositions that comprise transfersomes ranging in concentration from 0.1 to 99% of the total composition (column 4, lines 47-56). Therefore, the claim limitations "wherein the enhancing agent comprises, 1 part water, 1 part ethanol and 1 part polyethylene glycol " and "wherein the enhancing agent comprises 1 part of 10% and 0.9 part of a buffer" are taught by the prior art. Cevc teaches that the ethanol used is absolute ethanol (columns 55-56), therefore the ethanol taught by the prior art teaches the claim limitation "wherein the ethanol is 90% ethanol".

It would be *prima facie* obvious at the time the invention was made to incorporate the transfersomes as taught by Cevc into the transdermal patches of Yuzhakov et al because Cevc teaches that the transfersome compositions can be introduced to a permeability barrier such as the skin and can also be transported into deeper tissues when they become systemically active. It would be expected barring evidence to the contrary, that incorporating transfersomes into transdermal patches would be an effective way to facilitate the delivery of active agents such as botulinum toxin to a subdermal target of a patient.

Applicant's Arguments

Applicant urges that the Office has not established a case of *prima facie* obviousness because there is no motivation to combine the prior art references to arrive at the claimed invention. Applicant urges that one of ordinary skill in the art would not be motivated to combine the use of the penetration enhancer with a microneedle patch because neither reference teaches or suggests the combination. Applicant urges that claims 36-38 and 41-43 recite specific ratios and amounts of water, ethanol, polyeylene glycol, transfersomes and buffer and neither of the cited references teach these specific ratios.

Examiner's Response to Applicant's arguments

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Yuzhakov et al teach a transdermal patch comprising a pharmaceutical composition which comprises a botulinum and microneedles. Yuzhakov et al do not teach an enhancing agent such as transfersomes. However, Cevc teaches that tranfersomes can be used for transporting agents into natural barriers such as the skin (see the Abstract). Cevc et al also teaches that transfersomes have advantages over delivery vehicles such as liposomes because transfersomes can contain arbitrary amphiphile such as oils, transfersomes can be made in an arbitrary fashion such that their penetration does not depend upon how they were manufactured and transfersomes ensures a sufficiently higher permeation capability of each carrier (column 4). Thus, one of skill in the would be motivated to combine the teachings of Yuzhakov et al with the teachings of Cevc because Cevc teaches that transfersomes offer a more uniform means of transport across permeability barriers of diverse agents (column 5). Cevc teaches that transfersomes thus offer an elegant, uniform and generally useful means of transport across permeability barriers for diverse agents. These newly developed carriers are perfectly suited for use in

human and animal medicine, dermatology, cosmetics, biology, biotechnology, agrotechnology and other fields. Cevc further teaches that a transfersome according to this invention comprises any carrier with a special capability to get or diffuse into or through a permeability barrier under the effect of a gradient and by so doing to transport material between the application and destination sites.

To address Applicant's comments regarding claims 36-38 and 41-43, it appears that these claims are directed to the process of preparing or making the claimed transdermal patch using specific ratios. It should be remembered that the claims are directed to a transdermal patch, a product. Cevc teaches compositions that comprise transfersomes ranging in concentration from 0.1 to 99% of the total composition (column 4, lines 47-56). Therefore, the claim limitations "wherein the enhancing agent comprises, 1 part water, 1 part ethanol and 1 part polyethylene glycol " and "wherein the enhancing agent comprises 1 part of 10% transfersomes and 0.9 part of a buffer" are taught by the prior art because Cevc teaches that ethanol and polyethylene glycol are edge active substances used to prepare the transfersomes (column 55-56 and column 9) and Cevc teaches that transfersomes contain a water-filled central core (column 4). Yuzhakov et al and Cevc as combined above disclose the claimed invention except for the specific ratios as recited in the claims. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to optimize ratios, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Status of Claims

5. No claims allowed.

Conclusion

6. Any inquiry of the general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (571) 272–1600.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Office Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for the Group 1600 is (571) 272-8300.

Any inquiry concerning this communication from the examiner should be directed to Vanessa L. Ford, whose telephone number is (571) 272-0857. The examiner can normally be reached on Monday – Friday from 9:00 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (571) 272-0864.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov./>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Vanessa L. Ford
Biotechnology Patent Examiner
May 20, 2006

NITA MINNIFIELD
PRIMARY EXAMINER